

September 29, 2006

The Honorable Henry Waxman
United States House of Representatives
Washington, DC 20515

Dear Representative Waxman:

The Generic Pharmaceutical Association (GPhA) strongly supports the “Access to Life Saving Medicines Act,” which creates a viable abbreviated pathway for approval of generic versions of biopharmaceuticals. Enactment of this important legislation will increase access and lower the health care costs for all Americans by finally fostering competition in the biopharmaceutical marketplace. GPhA thanks you for your continued leadership and your efforts to ensure access to affordable medicines.

Biopharmaceuticals are the fastest growing sector of prescription drug expenditures in the United States. Americans should not be forced to continue to pay high brand prices for drugs even after patents on these products have expired due to the lack of an effective generic approval process. Generic biopharmaceuticals will not only provide patients with the same health benefits as their brand counterparts, but also yield significant cost savings for consumers, businesses, health plans and those who help them manage their prescription drug costs. For example, the European Union estimates that it will save \$2.8 billion in 2006 with the introduction of just a few biopharmaceuticals approved under an abbreviated pathway.

In addition, as the use of these medicines increases, generic biopharmaceuticals will be critical to containing future expenditures on Medicare, Medicaid and other federal health care programs. A recent review of 2005 Medicaid data found a 16 percent annual growth rate in biopharmaceutical prescriptions in that program. This translates into nearly \$6 billion spent on biopharmaceuticals in Medicaid during 2005, representing about one-fifth of the total program drug expenditures. With the utilization of biopharmaceutical products expected to increase in the near future, even modest savings from generic competition will help keep federal healthcare programs sustainable.

It is time for Congress to make certain that FDA takes prudent steps to ensure that affordable generic biopharmaceuticals get to market in a timely fashion and thereby increases consumer access to these safe and effective medicines. We thank you for introducing this legislation which is so critical to consumers and look forward to working with you to obtain bipartisan support and passage.

Sincerely,



Kathleen Jaeger
President and CEO